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PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|-----------------------------|---|------------------------|
| In re Application of: |) | |
| |) | |
| Takashi KOIKE |) | Confirmation No.: 3328 |
| |) | |
| Application No.: 10/546,828 |) | Group Art Unit: 2112 |
| |) | |
| Filed: August 25, 2005 |) | Examiner: Iyabo Alli |
| |) | |
| For: MEASURING DEVICE FOR |) | |
| IMMUNOCHROMATOGRAPHY TEST |) | |
| PIECE |) | |

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Window
Alexandria, VA 22314

Sir:

**SUBMISSION OF INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

Applicant brings to the attention of the Examiner the attached document.

Attached is an English-language translation of an International Preliminary Examination Report ("IPER"), including PCT/IB/373 and English translation of PCT/ISA/237, dated March 2, 2006 that issued in a related PCT/JP2004/001921 application. Applicant respectfully requests that the Examiner consider the IPER as it relates to the above-identified application.

The documents cited in the IPER were previously submitted in the instant application with an Information Disclosure Statement on August 25, 2005, and are therefore not submitted at this time.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed document is material or constitute "prior art." If it should be determined that the listed document does not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0573. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

DRINKER, BIDDLE & REATH LLP

Dated: January 10, 2007

By: 

John G. Smith

Registration No. 33,818

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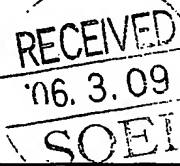
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NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

HASEGAWA, Yoshiki
Soel Patent And Law Firm
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Chuo-ku
Tokyo, 1040061
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Ginza First Bldg.



| | |
|--|---|
| Date of mailing (day/month/year) 02 March 2006 (02.03.2006) | |
| Applicant's or agent's file reference FP04-0003-00 | IMPORTANT NOTIFICATION |
| International application No. PCT/JP2004/001921 | International filing date (day/month/year) 19 February 2004 (19.02.2004) |
| Applicant — HAMAMATSU PHOTONICS K.K. et al | |

1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.



| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer Yoshiko Kuwahara |
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| | | |
|--|--|--|
| Applicant's or agent's file reference FP04-0003-00 | FOR FURTHER ACTION | See item 4 below |
| International application No. PCT/JP2004/001921 | International filing date (<i>day/month/year</i>) 19 February 2004 (19.02.2004) | Priority date (<i>day/month/year</i>) 26 February 2003 (26.02.2003) |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | |
| Applicant HAMAMATSU PHOTONICS K.K. | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35 | Date of issuance of this report 22 February 2006 (22.02.2006) |
| | Authorized officer Yoshiko Kuwahara Telephone No. +41 22 338 90 90 |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

Translation

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **20.04.2004**

Applicant's or agent's file reference

FP04-0003-00

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/001921

International filing date (day/month/year)

19.02.2004

Priority date (day/month/year)

26.02.2003

International Patent Classification (IPC) or both national classification and IPC

G01N21/17

Applicant

HAMAMATSU PHOTONICS K.K. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/001921

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

This opinion has been established on the basis of a translation from the original language into the following language

_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☐

in written format

☐

in computer readable form

c. time of filing/furnishing

☐

contained in the international application as filed.

☐

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/001921

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims 1-10 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims | YES |
| | Claims 1-10 | NO |
| Industrial applicability (IA) | Claims 1-10 | YES |
| | Claims | NO |

2. Citations and explanations:

Document 1: JP 59-120939 A (Merck Patent GmbH.), 12 July 1984

Document 2: JP 2002-098631 A (Matsushita Electric Industrial Co., Ltd.), 05 April 2002

Document 3: JP 11-083745 A (Matsushita Electric Industrial Co., Ltd.), 26 March 1999

Document 4: JP 50-003683 A (Konishiroku Shashin Kogyo Kabushiki Kaisha), 16 January 1975

Claims 1, 3 and 6

Document 1 discloses a device for evaluating chromatographic test pieces, which is equipped with photodiodes that receive the light reflected from the chromatographic test pieces and a plurality of light guide paths that are configured from optical fibers. In addition, document 1 also discloses a feature wherein the aforementioned plurality of light guide paths are disposed in parallel in a direction intersecting the direction in which the sample flows (fig. 1 and page 4, upper left column, line 15 to upper right column, line 9).

Document 2 discloses a device for evaluating chromatographic test pieces, wherein the objects to be

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement

evaluated are immunochromatographic test pieces.

Document 3 discloses a device for evaluating chromatographic test pieces, which comprises a housing of a light shielding material with optical paths for guiding a portion of the light from the immunochromatographic test pieces to the aforementioned photodiodes.

Furthermore, document 3 also discloses a feature wherein the aforementioned optical paths are configured from holes (corresponding to the "hole sections" in the present invention) that have been formed in the aforementioned housing.

Therefore, it would be easy for a person skilled in the art to evaluate the objects that are taught in document 2 in the device that is disclosed in document 1. Likewise, it would also be easy for a person skilled in the art to substitute the optical paths configured from holes that have been formed in the light-shielding material, which are taught in document 3, for the optical paths configured from optical fibers in the invention that is disclosed in document 1.

Consequently, the inventions that are set forth in claims 1, 3 and 6 do not involve an inventive step in the light of documents 1 to 3.

Claims 2 and 4

Document 1 also discloses a feature wherein the area of the test piece which is recorded by means of a sensor comprising separate light transmission members is small enough that it is possible to uniformly examine the concentration distribution within said area

(corresponding to the feature wherein the "width of the optical path is less than or equal to the width of the

Box No. V

Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement

strip-shaped colored section" in the present invention)
(page 3, lower left column, lines 8 to 11).

Consequently, the inventions that are set forth in claims 2 and 4 do not involve an inventive step in the light of documents 1 to 3.

Claim 5

Document 1 also discloses a feature wherein the number of photodiodes is the same as the number of optical paths (page 4, right column, lines 7 to 8).

Consequently, the invention that is set forth in claim 5 does not involve an inventive step in the light of documents 1 to 3.

Claim 7

Document 2 also discloses a device for evaluating chromatographic test pieces, which evaluates the light that passes through the chromatographic test pieces (page 3, left column, lines 26 to 33).

Therefore, it would be easy for a person skilled in the art to evaluate the light that traverses the chromatographic test pieces, as taught in document 2, in the device that is disclosed in document 1.

Consequently, the invention that is set forth in claim 7 does not involve an inventive step in the light of documents 1 to 3.

Claim 8

Document 2 also discloses a scanning means which moves the immunochromatographic test pieces relative to the optical detection system in a direction that is parallel to the direction in which the sample moves (page

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

3, right column, lines 28 to 34).

Therefore, it would be easy for a person skilled in the art to employ the scanning means that is taught in document 2 in the device that is disclosed in document 1.

Consequently, the invention that is set forth in claim 8 does not involve an inventive step in the light of documents 1 to 3.

Claim 9

Document 4 discloses a device for evaluating the concentration of a substance upon a test piece, wherein a plurality of optical detection systems are disposed in rows in order to simultaneously evaluate a plurality of substances (page 3, lower left column, lines 5 to 8).

Therefore, it would be easy for a person skilled in the art to employ the configuration wherein a plurality of optical detection systems are disposed in rows, which is taught in document 4, in the device that is disclosed in document 1.

Consequently, the invention that is set forth in claim 9 does not involve an inventive step in the light of documents 1 to 4.

Claim 10

Document 3 discloses a light emitting diode for emitting light towards the chromatographic test pieces and a tray for mounting the immunochromatographic test pieces (corresponding to the "table" in the present invention) (fig. 2).

Therefore, it would be easy for a person skilled in the art to employ the light emitting diode and the tray that are taught in document 3 in the device that is

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/001921

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability,
citations and explanations supporting such statement

disclosed in document 1.

Consequently, the invention that is set forth in
claim 10 does not involve an inventive step in the light
of documents 1 to 3.

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